Testimony on H1936, an Act relative to Genetically Engineered Food; H2037.
An Act to establish guidelines for genetically engineered food; and H2093, An Act relative to the labeling of food
before the Joint Committee on Public Health
Boston, MA
By
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June 11, 2013

Dear Committee members,

Thank you for the opportunity to present testimony in support of H1936, H2037, and H2093, all bills that would require the labeling of food and food products derived from genetically engineered (GE) organisms. My name is Michael Hansen and I am a biologist at Consumers Union1[1] (CU), the policy and advocacy arm of Consumer Reports. I have worked on the issue of genetically engineered foods for more than 20 years and have been involved in the decisions/debate about these foods at the state, national and international levels.

There is global agreement that genetic engineering is different than conventional breeding and that safety assessments should be completed for all GE foods prior to marketing. The human safety problems that may arise include introduction of new allergens or increased levels of naturally occurring allergens, of plant toxins, and changes in nutrition. There may also be unintended effects. Codex Alimentarius, the food safety standards organization of the United Nations, developed a number of documents, including a Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants (CAC/GL 45, 2003); there are separate Guidelines for GE animals (CAC/GL 68, 2008) and GE microorganisms (CAC/GL 46, 2003), as well.[2]

The United States, however, unlike all other developed countries, does not require safety testing for GE plants (although it does require an assessment for GE animals). The US Food and Drug Administration's (FDA) original policy on GE (or GM, for genetically modified) plants, developed more than twenty years ago,[3] says that companies may go through a "voluntary safety consultation." But, in the end, FDA says it is up to the companies to determine safety of any GE food. To date, there have been some 97 "voluntary safety consultations."

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[1] Consumers Union is the public policy and advocacy division of Consumer Reports. Consumers Union works for telecommunications reform, health reform, food and product safety, financial reform, and other consumer issues. Consumer Reports, a non-profit, is the world's largest independent product-testing organization. Using its more than 50 labs, auto test center, and survey research center, the nonprofit rates thousands of products and services annually. Founded in 1936, Consumer Reports has over 8 million subscribers to its magazine, website, and other publications.

[2] At: http://www.codexalimentarius.net/web/standard_list.do?lang=en

[3] Pg. 22991 in FDA. Statement of Policy: Foods Derived From New Plant Varieties, May 29, 1992, *Federal Register* vol. 57, No. 104. At: http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/Biotechnology/ucm096095.htm

The inadequacy of FDA's policy can be seen in the letter FDA sends to the company after completion of a "safety consultation." For example, the letter sent to Monsanto on July 22, 2004 about their RoundUp resistant wheat, MON 71800 (recently identified as the strain detected in wheat in Oregon), states, "Based on the safety and nutritional assessment you have conducted, **it is our understanding that Monsanto has concluded that wheat grain and forage derived from the new variety are not materially different in composition, safety, or other relevant parameters from wheat grain and forage currently on the market, and that the genetically engineered wheat does not raise issues that would require premarket review or approval by FDA**" (**bold** added).[4]

The letters for all 97 "safety consultations" contain basically the same language. This clearly shows that the FDA has not made a conclusion about the safety for genetically engineered (GE) plants or the safety of the technology as a whole.

Just last June, the American Medical Association's House on Delegates voted to change its policy on "bioengineered" foods to one that states: "**Our AMA supports mandatory pre-market systematic safety assessments of bioengineered foods** and encourages: (a) development and validation of additional techniques for the detection and/or assessment of unintended effects; (b) continued use of methods to detect substantive changes in nutrient or toxicant levels in bioengineered foods as part of a substantial equivalence evaluation; (c) development and use of alternative transformation technologies to avoid utilization of antibiotic resistance markers that code for clinically relevant antibiotics, where feasible; and (d) that priority should be given to basic research in food allergenicity to support the development of improved methods for identifying potential allergens."[5] **bold** added.

There is considerable evidence of health issue with GE foods. FDA is poised to approve a GE salmon, engineered to reach market weight in half the time of wild salmon. However, company data suggest that it may exhibit increased allergenicity.[6]

One big problem with safety assessments of GE plants is that there have been virtually no long-term animal feeding studies, with most feeding studies being of 90 days or shorter. A carefully designed meta-analysis of 19 published studies involving mammals fed GE corn or soy found damage in the kidney, liver and bone marrow, which could be potential indicators for the onset of chronic diseases.[7] However, no animal tests are obligatory for any of the GMOs cultivated on a large scale in the US.

A long-term (two year) feeding study published in October, 2012 found that females rats fed the GE corn died 2-3 times more quickly, and developed mammary tumors more often than

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[4] At: http://www.fda.gov/Food/FoodScienceResearch/Biotechnology/Submissions/ucm155752.htm

[5] http://www.ama-assn.org/resources/doc/yps/ref-comm-e-grid.pdf

[6] Hansen, M. 2010. Submission to FDA's Veterinary Medicine Advisory Committee meeting on safety assessment of AquAdvantage Salmon. http://www.consumersunion.org/wp-content/uploads/2013/02/CU-comments-GE-salmon-0910.pdf

[7] Séralini, G-E, Mesnage, R., Clair, E., Gress, S., de Vendômois, JS and D. Cellier. 2011. Genetically modified crops safety assessments: present limits and possible improvements. *Environmental Sciences Europe*, 23: 10. At: http://www.enveurope.com/content/pdf/2190-4715-23-10.pdf

controls who ate non-GE corn, while male rats fed the GE corn have liver and kidney problems at higher rate than controls, and more large tumors than rats fed non-GE corn.[8] The study, by Dr. Eric-Giles Séralini and colleagues was viciously attacked in the media by pro-GE and industry-affiliated scientists in what appear to have been an orchestrated campaign.[9]

The two main criticisms of the Séralini et al. study were that they used too few rat per group and that they used a strain of rat (Sprague Dawley, aka SD) that is prone to mammary tumors as they age. Both criticisms are off base. This study took blood and other biochemical measurements on 10 rats per group, the same number of rats that Monsanto took measurements on in their 90 day feeding study, which was published in the same journal eight years before the Séralini study. If ten rats is too small a sample size to demonstrate health problems, how come ten rats is a sufficient sample size to demonstrate no safety concerns? As for the strain of rat use, Séralini used the same strain (Sprague Dawley) that was used in the Monsanto feeding study. In addition, the same strain of rat was used in a Monsanto-sponsored two-year feeding study of rats fed glyphosate as part of a reregistration process in Europe. Why is use of SD rats bad when Séralini uses them, but ok when Monsanto and other biotech companies use them?

Both the French Food Safety Agency (ANSES) and the European Food Safety Authority (EFSA) have concluded that such long-term safety assessment should be done on GE foods. Indeed, the ANSES report on the Séralini study notes, "ANSES recommends initiating studies and research on the long-term effects of GMOs in combination with plant protection products … [and] calls for public funding on the national and European level to enable large-scale studies and research for consolidating knowledge of insufficiently documented health risks."[10] At a meeting in December, the "EFSA board meeting on Thursday last week there was agreement that long-term studies were needed and it was now just a question of how to fund them."[11] If the Séralini study is so flawed, why have ANSES and EFSA functionally agreed with its call for independently-funded long-term feeding studies on GE crops?

Just today, another long-term feeding study, this one involving US pigs fed a combination of GE corn and GE soy, has found evidence of adverse health effects. This well designed study involved a large sample size of pigs (168) raised in a commercial US piggery, and fed commercially available soy and corn for 22.7 weeks (the normal lifespan of commercial pig from weaning to slaughter) was designed "to compare the effects of eating either a mixed GM soy and GM corn diet, or an equivalent diet with non-GM ingredients."[12] The study found

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[8] Séralini et al. 2012. Long term toxicity of a Roundup herbicide and a Roundup-tolerant genetically modified maize. *Food and Chemical Toxicology*, 50: 4221-4231. http://www.sciencedirect.com/science/article/pii/S0278691512005637

[9] Bardocz S, Clark A, Ewen S, Hansen, M, Heinemann J, Latham J, Pusztai A, Schubert D and A Wilson. 2012. Séralini and science: An open letter. *Independent Science News*. At: http://independentsciencenews.org/health/seralini-and-science-nk603-rat-study-roundup/

[10] Reaction of ANSES (French Agency for food, environmental and occupational health and safety) to Séralini et al. study http://www.anses.fr/Documents/PRES2012CPA20EN.pdf

[11] Commission and EFSA agree need for two-year GMO feeding studies. EU Food Policy, 17 December 2012 http://www.eufoodpolicy.com/cgi-bin/view_article.pl?id=5590

[12] Pg. 40 in Carman JA, Vlieger HR, Ver Steeg LJ, Sneller VE, Robinson GW, Clinch-Jones CA, Haynes JI and JW Edwards. 2013. A long-term toxicology study on pigs fed a combined genetically modified (GM) soy and GM maize diet. *Journal of Organic Systems* 8(1): 38-54. At: http://www.organic-systems.org/journal/81/8106.pdf

that the uteri of GE-fed pigs was significantly larger (weighed 25% more) than those non-GE-fed pigs. In addition, the rate of severe stomach inflammation was more than 2.5-fold higher, on average, for GE-fed pigs compared to non-GE-fed pigs (32% vs 12%, respectively). Indeed, for male pigs, the rate of severe stomach inflammation was four times higher for GE-fed males to non-GE fed males, and for females, the rate was more than 2-fold higher. As the authors conclude "The results indicate that it would be prudent for GM crops that are destined for human food and animal feed, including stacked GM crops, to undergo long-term animal feeding studies preferably before commercial planting, particularly for toxicological and reproductive effects."[13]

In addition, there is virtually no independent safety testing of these crops in the US due to intellectual property right problems. When farmers buy GE seed in the US, they invariably must sign a product stewardship agreement which forbids them from giving such seeds to researchers.[14] Since researchers must get permission from the biotech companies before they can do research, the result is a paucity of independent research. Scientists have even been threatened with legal action if they revealed information obtained via freedom-of-information.[15] In early 2009 26 public sector scientists in the US took the unprecedented step of writing to the US Environmental Protection Agency (EPA) protesting that "as a result of restricted access, no truly independent research can be legally conducted on many critical questions regarding the technology."[16] As a result, the editors of *Scientific American* published a perspective stating that "we also believe food safety and environmental protection depend on making plant products available to regular scientific scrutiny. Agricultural technology companies should therefore immediately remove the restriction on research from their end-user agreements." We concur and believe that only truly independent safety tests will give us an answer about the safety of GE foods. In the meantime, it's crucial that GE foods be labeled, so that if people experience negative effects, they and their doctors can identify them.

Because of these safety questions raised by the long-term feeding studies, because of the allergy issues, and because consumers have a basic right to know that they are eating, CU supports labeling of GE food. Finally, at least 62 countries, which together include more than half the world's population, (including all European Union, China, India, Japan, Korea, Australia, Russia, Brazil and South Africa), require labeling of GE foods.[17] A number of polls from 1995 to 2011 have found that between 70% and 95% of Americans polled supported mandatory labeling.[18] Such labeling is important because consumers have a right to choose the foods they eat and to avoid any unintended health effects.

Finally, we urge the Committees to consolidate H1936, H2037 and H2093 into a single bill. We urge you to use the definition of "genetically engineered" found in the H2037, since it is the definition used globally in Codex Alimentarius, and in the GE labeling bills in neighboring states (Vermont and Maine). Bottom line, CU supports mandatory labeling of GE foods and so supports H1936, H2037 and H2093.

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[13] Pg. 52 in IBID.
[14] Waltz, E. 2009. Under wraps. Nature Biotechnology, 27(10): 880-882. At: http://www.emilywaltz.com/Biotech_crop_research_restrictions_Oct_2009.pdf
[15] IBID
[16] http://www.scientificamerican.com/article.cfm?id=do-seed-companies-control-gm-crop-research
[17] See http://www.centerforfoodsafety.org/ge-map/
[18] http://gefoodlabels.org/gmo-labeling/polls-on-gmo-labeling/